

REMARKS

Claims 1-26 are pending in this application. Claims 1-12 and 19-24 have been previously withdrawn from consideration. By this Amendment claims 17 and 18 are amended, claims 13-16 and 25-26 are cancelled, and claims 27-32 are new.

Reconsideration and allowance in view of the following amendments and remarks are requested.

Support for the amended claims and the new claims can be found in the specification and claims as originally filed. For example, support for the amended claims 17 and 18 can be found in original claim 13 and in the specification at paragraph [0044] (the film selected to dissolve in the oral cavity within 15 seconds of application). Support for the new claims 27-30 is found in original claims 25 and 26. Support for the new claims 31-32 is found in paragraph [0057] of the specification. The amended claims and new claims introduce no new matter, and thus, their entry is respectfully requested.

Claim Rejections – 35 U.S.C. § 102

Claims 13 and 25 stand rejected under 35 U.S.C. § 102(b), as being anticipated by WO98/20861 ("Brown"). Claim 13-16 and 25-26 stand rejected under 35 U.S.C. § 102(b), as being anticipated by WO00/59423 ("Acharya"). While Applicants disagree with the rejections, to advance this application to issue, Applicants cancel claims 13-16 and 25-26 and reserve the right to pursue said claims in the future.

Claim Rejections – 35 U.S.C. §103(a)

Claims 13-18 and 25-26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over WO98/20861 ("Brown") or WO00/59423 ("Acharya") in view of US 7025983 ("Lueng").

As set forth above, while Applicants disagree with the rejections regarding claims 13-16 and 25-26, to advance this application to issue, Applicants cancel claims 13-16 and 25-26 and reserve the right to pursue said claims in the future.

As amended, claims 17 and 18 recite in part "providing an edible film, wherein the edible film consists essentially of a film layer and a powder matrix coating." Brown et al. discloses "applying an active coating material to a surface of a substrate form" and "applying a cover coating material onto the active coating layer." Brown at 4, lines 1-8. Brown further states that "[i]t is preferable for the cover coating to cover completely all of the active coating, but incomplete coating, for example at the edge of the active coating layer, may be tolerated in some circumstances." Brown at 5, lines 10-13. Thus Brown requires a substrate, an active coating layer, and a cover coating to, for example, "protect" or provide for "delayed release" of the active coating layer. Brown at 4, line 27-5, line 9. Brown does not teach "providing an edible film, wherein the edible film consist essentially of a film layer and a powder matrix coating" as claimed. One skilled in the art would not modify the two coatings and substrate of Brown in the claimed manner in view of Brown's teaching to the contrary. Accordingly, the combination of Brown and Leung does not teach or disclose the claims 17 or 18.

Moreover, as amended, claims 17 and 18 recite in part "wherein the edible film is configured to dissolve in the oral cavity within 15 seconds of application." To the

contrary, Acharya is directed to "a laminated active substance delivery device comprising a layer of mucoadhesive composition consisting primarily of PVP without a plasticizer.... Such non-plasticized PVP mucoadhesives provide for localization of the active substance-containing delivery device over a sustained period...." Acharya at 6, lines 25-31. Acharya further criticizes other delivery mechanisms, such as lozenge, troche, breath freshener or mouthwash, as "remaining in the oral cavity only for short periods of time, generally not more than about 10-20 minutes." Acharya at 2, lines 25-31. One skilled in the art would not look to a disclosure directed to sustained delivery using a film requiring "non-plasticized PVP" as disclosed in Acharya as teaching or relating to an edible film "wherein the edible film is configured to dissolve in the oral cavity within 15 seconds of application" comprising "pectin" or having the formulations as claimed. Moreover one skilled in the art would not combine such a disclosure with that of Lueng for the same reasons.

Claims 17 and 18 as amended further recite in part "wherein at least one of the film layer and the powder matrix coating comprises benzocaine." Neither Brown nor Leung disclose the use of benzocaine, let alone the use of benzocaine for the treatment of pharyngitis as claimed. As set forth above one skilled in the art would not look to the disclosure of a "delivery device over a sustained period," as disclosed in Acharya, to remedy said deficiency.

Because new claims 27-32 depend on claims 17 or 18, said claims are patentable for at least the same reasons set forth above.

In view of the foregoing, it is submitted that the claims are in condition for allowance. A Notice of Allowance is respectfully requested.

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Respectfully submitted,

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